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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

7590 03/31/2005

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,20,22-51,53 and 54* is/are pending in the application.

4a) Of the above claim(s) *41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,20,22-40,45-51,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JL

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Amendment filed 11/22/04.

Election of Species

Applicant's election without traverse of fluvoxamine in the reply filed on 11/22/04 is acknowledged.

Claims 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/22/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Eudragit® being a rate release coating polymer at 4%, 6%, 8%, 10.0%, 12% and 15%, does not reasonably provide enablement for any rate-controlling polymer at any percent amount. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. It appears from the specification at page 24, tables 4 and 19, that only Eudragit® in an

amount of 4%, 6%, 8%, 10.0%, 12% or 15% will exhibit the release rates claimed in claims 23, 24 and 28-30.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 54 is rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al. US 5,958,458.

Norling teaches a pharmaceutical multiparticulate formulation in the form of coated cores (abstract). The core is in the form of pellets, comprising active agent and excipient (columns 2, lines 33-42; and column 13, lines 29-67). The active agent includes antidepressants (column 6, lines 35-40). The coated multiparticulate is formulated into oral solid dosage form including tablet, capsule, powder or granule suitable to release active agent during a 24 hours period (column 13, lines 20-36). Suitable coating polymers includes ethyl cellulose, Eudragit® E, Eudragit® RS or RL, polyvinyl acetate phthalate (columns 9-10).

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses

and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly, it is the position of the examiner that the release profile is inherent because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 20, 22-40, 45-51, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780.

Norling is relied upon for the reason stated above. Norling is silent as to the specific teaching of antidepressant drug, such as fluvoxamine.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, *e.g.*, fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify pharmaceutical multi-particulate formulation of Norling using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated

beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Accordingly, it is the position of the examiner that the release profile is inherent because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Response to Arguments

Applicant's arguments filed 11/22/04 have been fully considered but they are not persuasive.

Applicant argues that while the application may not disclose specifically formulations which exhibit the release profile claimed other than those in which Eudragit® is used as the coating polymer, all one skilled in the art would have to do to determine which of these polymers may be used and in which thickness they may be

used to achieve the desired release profile is to test SSRI-containing cores coated with the polymer of interest at the thickness of interest in the apparatus specified by the claims under the conditions specified by the claims to see whether the polymer and the thickness thereof would allow for the desired release profile, even if such experimentation is considered tedious, "[the] fact that experimentation may be complex does not necessarily make it undue, it the art typically engages in such experimentation." MPEP § 2164.01. However, the test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). According to applicant's argument, it is not just experimentation is necessary, but *tedious* experimentation is necessary, thus, the specification does not enable one skilled in the art to make and use the invention as claimed without resorting to undue experimentation. It has been required that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Accordingly, the 112, first paragraph rejection of claims 23, 24 and 28-30 is maintained.

Applicant argues that Van Balken does not disclose specifically any fluvoxamine-containing formulation and merely list fluvoxamine as a potential active agent for use in the formulations disclosed therein. More importantly, Van Balken does not disclose any extended release formulation at all. Therefore, one skilled in the art would not have been motivated to combine the teaching of Van Balken with that of Norling. However, the test for obviousness is not whether the features of a secondary reference may be

bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Van Balken is relied upon solely for the teaching of an antidepressant includes fluvoxamine.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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